IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN N-NITROSODIMETHYLAMINE (NDMA) CONTAMINATION PRODUCTS LIABILITY LITIGATION	Civil No. 19-2875 (RBK/JS)

ORDER

The Court having conducted a conference with the parties on April 24, 2019; and this Order intending to confirm the Court's rulings regarding the production of "core discovery"[1] and other issues; and good cause existing for the entry of this Order; and accordingly,

IT IS HEREBY ORDERED this 29th day of April, 2019, as follows:

1. This Order regarding the production of "core" discovery shall only apply to API manufacturer and supplier defendants. This Order shall also apply to finished product/dose manufacturer defendants. Hereinafter, these defendants shall be collectively referred to as the "responding defendants." To the extent core discovery is not produced by the responding defendants, defendants who are U.S. agents for the purpose of FDA communications shall produce the discovery.

2. The responding defendants shall only produce core discovery concerning the facilities that manufactured the API used in Valsartan or the finished products at issue in the litigation. The responding defendants shall also produce a list of the

[1] The Court defines "core discovery" as discovery that is (1) easily identifiable, (2) unquestionably relevant and not privileged, (3) relatively simple to retrieve, and (4) discrete. The purpose of requiring the early production of core discovery without the necessity of a formal document request, is to help identify the genuine issues in dispute and to assist the parties in their effort to timely frame an acceptable ESI protocol. Even if a subject area does not meet the criteria of core discovery, it does not necessarily mean the area is off-limits to Fed.R.Civ.P. 26(b)(1) discovery.

responsive facilities.

3. At this time, the production of core discovery is limited to Valsartan and not Losartan or Irbesartan.

4. The documents identified herein shall be produced by no later than June 17, 2019. By no later than May 27, 2019, the Court shall be advised of the identity of any responding defendant who will not produce all or some of the documents listed herein on the ground they have not been properly served.

5. The responding defendants shall identify the Bates numbers of the documents responsive to each category of documents listed in paragraph 6 herein.

6. The responding defendants shall produce the following core discovery:

a) For API Manufacturer and Supplier Defendants

1. Valsartan ANDA file
2. Valsartan Drug Master File
3. Communications with the FDA relating to or concerning: (1) the ARB recalls, (2) the investigation into the cause of the alleged contamination, (3) efforts to contain, remove or detect the contamination, (4) supplements to the Valsartan Drug Master File re: manufacturing process changes from 2010 to present, (5) all FDA Form 483's, Establishment Inspection Reports, CGMP inspection reports, and warning letters, as well as the responding defendants' responses to same, regarding any facility that manufactured or supplied the API at issue, and (6) a list of all United States customers from 2010 to present.[2]
4. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.

b) For Finished Product/Dose Manufacturer Defendants

1. ANDA file for each involved finished dosage formulation

[2] The Court is aware some defendants started generic manufacturing after 2010.

2. Communications with the FDA described in paragraph 6.a.3.
3. To the extent not produced by another responding defendant, the discovery listed in paragraph 6.a.
4. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.

c) For U.S. Agents for FDA Communications Defendants

1. To the extent not produced by another responding defendant, the discovery listed in paragraphs 6.a. and b. above
2. To the extent a responding defendant contends it does not have possession, custody or control of any of the listed documents, it shall identify where the documents are located.

7. Without the need for a separate discovery request, and no later than seven (7) days after the date it sends to the FDA or receives from the FDA a communication regarding the (1) ARB recall, (2) the investigation into the cause of the alleged contamination, and (3) efforts to contain, remove or detect the contamination, the responding defendants shall serve plaintiffs with a copy of the responsive communication.[3]

8. The next status conference call is scheduled on May 8, 2019 at 3:00 p.m. Plaintiffs shall arrange the call. If not done beforehand, the Court expects to finalize during the call the terms of the Discovery Confidentiality Order to be entered.

[3] This provision is modeled after Local Patent Rule 3.6(j).

9. By the next in-person conference on May 29, 2019, the Court expects to finalize the parties' Profile Forms and Short Form Complaints, and an Order regarding the parties' group organization and leadership. All disputes regarding the ESI Protocol, except for the identity of the applicable custodians and search terms to be used, shall be identified before the May 29 conference.

s/ Joel Schneider
JOEL SCHNEIDER
United States Magistrate Judge

Dated: April 29, 2019